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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,223	12/27/2001	David Botstein	GNE.2930R1C9	7370

30313 7590 06/21/2005

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,223	BOTSTEIN ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-27,32-35 and 37-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-27,33-35 and 37-46* is/are rejected.

7)☒ Claim(s) *32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/4/2005 has been entered.

Claims 25-27, 32-35 and 37-46 are pending and under consideration.

The claims are drawn to nucleic acids encoding a protein identified as PRO1800.

Priority Determination:

The utility for the claimed nucleic acids is based upon Example 16, in which it is shown that the DNA exists in at least 2-fold higher copy amount in 6/9 of tested lung squamous cell carcinoma cell lines. No priority exists for that result in provisional application 60/112851. The earliest disclosure of this result that can be confirmed by the Examiner is in PCT/US99/28634, of which applicants have made of record a copy of the relevant portion. Accordingly, priority is set at 12/1/99.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26, 35, and 37-46 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid of SEQ ID NO: 1 or fragments of such that are usable as hybridization probes, does not reasonably provide enablement for degenerate variants of such, which might encode a similar protein, nor for nucleic

acids 80, 85, 90, or 95% identical to such, nor which encode a protein 80, 85, 90, or 95% identical to the protein of SEQ ID NO: 1, nor nucleic acids which hybridize to any of the above, any of the aforementioned which are overexpressed in lung or colon tumor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This rejection is maintained for reasons of record. Applicants arguments are largely duplicative of previous arguments, and those duplicative arguments are not persuasive for reasons of record. Applicants additionally argue at the bottom of page 9 of the response filed 4/4/2005 that the question of whether gene amplification is indicative of protein expression levels has been rendered moot in view of the amendments to the claims. This is true, however the remainder of the rejection is maintained for reasons of record. It is noted that applicants also feel that the recitation of hybridization conditions is significant; the Examiner does not agree, because (a) it is not likely that there exist any species that would meet the other claim limitations without also inherently meeting the hybridization limitations, even more so since (b) the recitation of hybridization conditions does not include the *time* of the wash step, which is critical to the stringency of the process.

Claims 25, 26, 35 and 37-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in the previous Office Action mailed 5/13/2004.

Applicants arguments are largely duplicative of previous arguments, and those duplicative arguments are not persuasive for reasons of record. Applicants additionally argue at pages 11-12 that the finding in the *Enzo* case would support the claimed invention having adequate written description. This argument has been fully considered but is not deemed persuasive because (a) the fact situation in the *Enzo* case is substantively different from that in the instant case; the *Enzo* claims are drawn to a "composition of matter that is specific for *Neisseria gonorrhoeae*", which is then further described by ATCC deposit number and sequences that hybridize to such. It is further noted that the hybridization recitation in *Enzo* is

substantively different than that herein, as it requires a comparative hybridization that demonstrates specificity of the claimed composition for one strain of *Neisseria* over another. By contrast, the instant claims have *no* functional limitations. Similarly, Example 9 of the Written Description guidelines is not applicable here, as the fact situation described therein is:

> The specification discloses a single cDNA (SEQ ID NO:1) which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. The specification includes an example wherein the complement of SEQ ID NO: 1 was used under highly stringent hybridization conditions (6XSSC and 65 degrees Celsius) for the isolation of nucleic acids that encode proteins that bind to dopamine receptor and stimulate adenylate cyclase activity. The hybridizing nucleic acids were not sequenced. They were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity. These sequences may or may not be the same as SEQ ID NO: 1.

The nucleic acids claimed herein are not required to encode a protein, much less one with adenylate cyclase or other well-characterized activity. Similarly, Example 14 is drawn to a protein with a well defined function, and a claim that is limited to 95% identity to the calimed sequence. The fact situation therein is substantively different from that of the instant application.

It remains that in the instant case, the specification teaches that PRO1800 has (unspecified) homology to) homology to Hep27, which Hep27 is a member of the short chain alcohol dehydrogenase protein family (page 2). At page 70, the specification states that PRO1800 is a Anewly identified Hep27 homolog, and possesses activity typical of that protein≅, however no activity is known or disclosed for Hep27. The structure of the putative PRO1800 peptide is discussed at page 103 of the specification, but includes disclosure that the protein is expected to be a transmembrane protein, nor disclosure of an extracellular domain. There is no biological activity, expression pattern, phenotype, disease or condition, ligand, binding partner, or any other specific feature that is disclosed as being associated with PRO1800.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion

of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Therefore, nucleic acids comprising the sequence set forth in SEQ ID NO:1, with or without the portion encoding the signal sequence, or fragments thereof sufficiently long to be used as hybridization probes but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Rejections Over Prior Art:

The effective priority date is 12/1/1999.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 25-27, 33-35 and 37-46 are rejected under 35 U.S.C. 102(a) as being anticipated by DE 198 18 620 (Rosenthal et al.), cited by applicants.

Rosenthal et al. disclose a nucleic acid, SEQ ID NO: 10, which is 100% identical to SEQ ID NO: 1 of the instant application, with the exception of nine nucleotides at the amino terminus of SEQ ID NO: 1, which is outside the coding region. A translation of pages 1-5 and 132-133 of Rosenthal is provided, in which it is disclosed that the invention includes vectors and host cells, and fusion constructs (see pages 3-4 of translation). The person of ordinary skill in the art would recognize that numerous of the vectors listed at page 3 of the translation are specific to *E. coli*. Accordingly, the claims are anticipated.

Claims 25-27, 33-35 and 37-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank locus AF044127, disclosed 5/27/1999. The clone is identical to nucleotides 11-terminus of SEQ ID NO: 1 of the instant application. It is disclosed as having been cloned in an M13 phage expression library, thus being an expression vector, and utilizing *E. coli* as a host cell strain. Accordingly, the claims are anticipated. Applicants argue at page 23-24 of the response that the Genbank disclosure does not qualify as a reference under 35 U.S.C. §102(b). This argument has been fully considered but is not deemed persuasive because of the priority determination made in this case, in which priority is granted only to 5/25/2001.

Claims 35, 37 and 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by F. Gabrielli et al., Eur. J. Biochem 232:473, 1995, cited by applicants. The Examiner thanks applicants for pointing out the omission of this rejection from the previous Office Action.

Gabrielli et al. teach a protein 62% identical to SEQ ID NO: 2, the nucleic acid encoding such having sufficient regions of identity to SEQ ID NO: 1 such as to hybridize to such, even under "stringent" conditions. The entire length of Gabrielli's nucleic acid is 1442 nucleotides. Accordingly, the claims are anticipated by Gabrielli et al.

Advisory Information:

No claim is allowed.

Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner

6/16/2005